BOARD OF DENTISTRY GENERAL BUSINESS MEETING AGENDA May 19, 2017

DoubleTree by Hilton Orlando Airport 5555 Hazeltine National Drive Orlando, Florida 32812 (407) 856-0100 7:30 A.M.

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

CALL TO ORDER/ROLL CALL I.

MEMBERS PRESENT

Joseph Thomas, DDS, Chair Catherine Cabanzon, RDH, BASDH, Vice Chair Joseph Calderone, DMD T.J. Tejera, DMD William Kochenour, DDS Robert Perdomo, DMD Angela Sissine, RDH Claudio Miro, DDS Naved Fatmi, DMD

STAFF PRESENT

Jennifer Wenhold, Executive Director Jessica Sapp, Program Administrator

BOARD COUNSEL

David Flynn, Esq. Assistant Attorney General

PROSECUTING ATTORNEY

Bridget McDonnell, Esq. Candace Rochester, Esq. Rose Garrison, Esq. Tobey Schultz, Esq.

COURT REPORTER

American Court Reporting Cindy Green (407) 896-1813 ReportingOrlando@aol.com

Tim Pyle, Consumer member

II. WREB PRESENTATION

Dr. Bruce Horn, Director of Dental Exams

Dr. Horn provided an overview of the Western Regional Examination Board (WREB) examine to the board. Dr. Thomas thanked Dr. Horn for attending and explained the exam requirements outlined in Chapter 466 and that a legislative change would be required to accept the WREB exam.

III. REVIEW OF MINUTES

A. February 17, 2017 Board Meeting

The minutes of the February 17, 2017 meeting were reviewed and the following action was taken by the Board:

Motion: by Dr. Kochenour to approve

Second: by Ms. Cabanzon

Vote: Unanimous

I. REPORTS

A. Board Counsel

i. Correspondence from the Florida Association of Nurse Anesthetists

Mr. Flynn provided this letter and his response as informational to the board.

ii. Rules Report

Mr. Flynn went explained the status of the open rules to the board.

Mr. Flynn requested that Rule 64B5-12.013, Continuing Education Requirements be discussed again at the next Rules Committee meeting to address the comments received by JAPC.

Motion: by Dr. Kochenour to place the rule on the next Rules Committee agenda

Second: by Dr. Calderone

Vote: Unanimous

iii. Annual Regulatory Plan 2016-2017

This was provided as reference material.

iv. Rule Making Timeline

This was provided as reference material.

v. Statement of Estimated Regulatory Cost (SERC) Summary

This was provided as reference material.

vi. SERC Checklist Form

This was provided as reference material.

B. Executive Director

i. Revised Delegation of Authority

After discussion, the following action was taken:

Motion: by Dr. Tejera to approve the delegation as presented

Second: by Dr. Calderone

Vote: Unanimous

Dr. Thomas requested that "on behalf of the board or board chair" be added to section three and four to provide further clarification.

ii. Financial Reports

This was provided as informational.

iii. Anesthesia Ratification List

Motion: by Dr. Tejera to approve Second: by Dr. Kochenour

Vote: Unanimous

C. Chairman

Dr. Thomas explained the upcoming changes to the NBDE, part I and II. This exam will be consolidated and referred to as the INBDE.

A legislative change will be required to confirm to these changes.

Dr. Kochenour requested that they review the licensure application to determine if any changes are required. Mr. Flynn will review and bring back any suggestions to the next board meeting. AADB meeting in October. Dr. Perdomo, Ms. Cabanzon and Dr. Fatmi plan to attend. The Board asked Mr. Flynn to attend as well.

D. Vice-Chairman

E. Board Members

i. Dr. Fatmi – Council on Dental Assisting Update

Dr. Fatmi provided the board with an overview of the April 13, 2017 Council on Dental Assisting conference call. The council discussed the different training requirements of Dental Assistants and decided to not make any changes to Rule 64B5-16.002 as it is up to the dentist to decide whether they want to hire an assistant from a CODA accredited school or someone with on the job training.

The council also discussed Rule 64B5-25.003, Sterilization requirements. This will again be discussed at the next council meeting.

II. DISCIPLINARY PROCEEDINGS

A. Informal Hearing Not Involving Disputed Issues of Material Fact

i. Marino Frank Vigna, DDS, Case No. 2016-13374(PCP – Thomas, Morgan, Fatmi)

Dr. Vigna was present and sworn in by the court reporter. He was represented by Joshua Fisher, Esq. Dr. Thomas recused himself from participating and voting in this case but received permission from Mr. Fisher to Chair the case.

Ms. Garrison summarized the case for the board. Respondent was charged with violating Section 456.072(1)(x), Florida Statutes, by failing to report to the Board within 30 days his plea of nolo contendere to the charge of grand theft.

Motion: by Ms. Cabanzon to find that the respondent was properly served and has

requested an informal hearing. Second: by Dr. Calderone

Vote: Unanimous

Motion: by Ms. Cabanzon to adopt the findings of fact as set forth in the Administrative

Complaint.

Second: by Dr. Tejera Vote: Unanimous

Motion: by Ms. Cabanzon to adopt the conclusions of law as set forth in the Administrative

Complaint and find that this constitutes a violation of the practice act.

Second: by Dr. Calderone

Vote: Unanimous

After discussion, the following action was taken:

Motion: by Dr. Tejera to impose a Letter of Concern, a \$500.00 fine to be paid within 90 days, costs of \$174.89 to be paid within 90 days, and successful completion of the Florida Laws and Rules exam within six months.

Second: Dr. Perdomo Vote: Unanimous

ii. Marino Frank Vigna, DDS, Case No. 2016-14511 and 2016-13367 (PCP – Thomas, Robinson, Fatmi)

Dr. Vigna was present and sworn in by the court reporter. He was represented by Joshua Fisher, Esq. Dr. Thomas recused himself from participating and voting in this case but received permission from Mr. Fisher to Chair the case.

Ms. Garrison summarized the case for the board. Respondent was charged with the following violations: **Count I:** Section 466.028(1)(mm), Florida Statutes, by violating Section 456.072(1)(kk), Florida Statutes for being terminated from the Florida Medicaid program. **Count II:** Section 466.028(1)(mm), Florida Statutes, by violating Section 456.072(1)(c), Florida Statutes for being convicted or found guilty of, or entering a please of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of a licensee's profession.

Motion: by Ms. Cabanzon to find that the respondent was properly served and has

requested an informal hearing. Second: by Dr. Kochenour

Vote: Unanimous

Motion: by Dr. Tejera to adopt the conclusions of law as set forth in the Administrative

Complaint and find that this constitutes a violation of the practice act.

Second: by Ms. Cabanzon

Vote: Unanimous

After discussion, the following action was taken:

Motion: by Ms. Sissine to impose a fine of \$2500.00 to be paid within 90 days to and issue

a Letter of Concern Second: Dr. Kochenour

Vote: 7/1

Motion: by Ms. Sissine to impose Costs of \$166.54 for Case No. 2016-14511 and \$1486.54

for Case No. 2016-13367 to be paid within 90 days.

Second: Dr. Tejera Vote: Unanimous

iii. Dora Marie Martin, DR, Case No. 2015-05496(PCP – Thomas, Cabanzon, Calderone)

Ms. Martin was present and sworn in by the court reporter. She was not represented by counsel. Dr. Thomas recused himself and requested Dr. Perdomo chair this tab.

Ms. McDonnell summarized the case for the board. Respondent was charged with violating Section 466.028(1)(mm), Florida Statutes through a violation of Section 456.072(1)(m), Florida Statutes, by making deceptive, untrue, or fraudulent representations in or related to her practice as a dental radiographer through the use of the dental employer's DEA license number in a scheme to obtain prescription medicine without authorization.

Motion: by Ms. Sissine to find that the respondent was properly served and has requested an informal hearing.

Second: by Dr. Kochenour

Vote: Unanimous

Motion: by Dr. Kochenour to adopt the findings of fact as set forth in the Administrative

Complaint.

Second: by Dr. Tejera Vote: Unanimous

Florida Board of Dentistry Meeting Minutes May 19, 2017 Motion: by Dr. Kochenour to adopt the materials under this agenda item and any

addendum materials into evidence in this proceeding.

Second: by Ms. Sissine

Vote: Unanimous

Motion: by Dr. Kochenour to adopt the conclusions of law as set forth in the Administrative

Complaint and find that this constitutes a violation of the practice act.

Second: by Ms. Sissine

Vote: Unanimous

After discussion, the following action was taken:

Motion: by Dr. Tejera to impose a reprimand and a fine of \$1000.00 fine to be paid within

24 months

Second: Dr. Kochenour

Vote: Unanimous

Motion: by Dr. Tejera to impose costs of \$2867.19 to be paid within 36 months

Second: by Dr. Kochenour

Vote: Unanimous

B. Settlement Agreements

i. Roxanne Malone-Winarski, DDS, Case No. 2011-11545 (PCP – Morgan, Stevens, Robinson)

Dr. Malone-Winarski was present and sworn in by the court reporter. She was represented by Randolph Collette, Esq.

Ms. McDonnell summarized the case for the board. Respondent was charged with the following violations: **Count I:** Section 466.028(1)(g), Florida Statutes, by aiding or assisting an unlicensed person to practice dentistry. **Count II:** Section 466.028(1)(z), Florida Statutes, by delegating professional responsibilities to a person who is not qualified by training, experience, or licensure to perform them. **Count III:** Section 466.028(1)(x), Florida Statutes, by being guilty of incompetence or negligence by failing to meet the minimum standards of performance in diagnosis and treatment when measured against generally prevailing peer performance.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Letter of Concern
- \$2,500.00 fine to be paid within twelve (12) months
- Costs of \$3,743.89 to be paid within thirty (30) days
- Level I Implants course completed through an accredited college of dentistry within twelve (12) months.
- Successful completion of the Laws and Rules exam within twelve (12) months

After discussion, the following action was taken: Motion: by Dr. Thomas to dismiss the case

Second: by Dr. Tejera Vote: Unanimous

ii. Nelson Roberto Marques, DDS, Case No. 2013-13083 and 2014-06823 (PCP – Thomas, Britten, Fatmi)

Dr. Marquez was present and sworn in by the court reporter. He was represented by Randolph Collette, Esq.

Mr. Schultz summarized Case No. 2013-13083 for the board. Respondent was charged with the following violations: **Count I:** Section 466.028(1)(m), Florida Statutes, by failing to maintain written records on each patient. **Count II:** Section 466.028(1)(x), Florida Statutes, by failing to perform a diagnosis of the periodontal health of the patient prior to treatment of scaling and root planning; by failing to adequately seat and verify the fit of permanent crowns to avoid open margins; and by failing to adequately diagnose the patient's dental condition and develop an appropriate treatment plan.

Mr. Schultz summarized Case No. 2014-06823 for the board. Respondent was charged with the following violations: Count I: Section 466.028(1)(m), Florida Statutes, by failing to keep a written dental record containing any dental charting or identification of existing decay. missing, and/or filled teeth, and other oral conditions; by failing to keep a written dental record containing a proposed treatment plan; by failing to keep a written dental record of the diagnosis or justification for the prescription of an antibiotic and pain reliever; by failing to keep a written dental record documenting the delivery of a crown; by failing to keep a written dental record documenting the type of prosthetic bridge; by failing to keep a written dental record of the dental treatment provided; and by failing to keep a written record of the impression made in preparation of the prosthetic bridge. **Count II:** Section 466.028(1)(x), Florida Statutes, by failing to take a panoramic radiograph or full mouth series before proceeding with implant placement; by failing to diagnose the presence of a periapical radiolucency; by failing to diagnose open margins on patient's existing crown restorations; by failing to diagnose patient's bruxism condition; by failing to provide appropriate treatment for patient's dental treatment; and by failing to diagnose peri-implantitis associated with the implant; by failing to properly adjust the prosthetic bridge placed.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Reprimand
- \$10,000.00 fine to be paid within twenty-four (24) months
- Costs of \$8,000.00 to be paid within twenty-four (24) months
- Level I Crown and Bridge course completed through an accredited college of dentistry within twelve (12) months.
- Level I Implants course completed through an accredited college of dentistry within twelve (12) months.
- Level I Record Keeping course completed through an accredited college of

- dentistry or through a Board-approved continuing education provider within twelve (12) months.
- Patient reimbursement of out-of-pocket fees and third party reimbursement if applicable, within twenty-four months
- Successful completion of the Laws and Rules exam within twenty-four months

After discussion, the following action was taken:

Motion: by Dr. Thomas to reject Second: by Dr. Calderone

Vote: Unanimous

Motion: by Dr. Thomas made a motion to offer the following counter agreement:

- Appearance
- Reprimand
- \$2,500.00 fine to be paid within twenty-four (24) months
- Costs of \$8,000.00 to be paid within twenty-four (24) months
- Successful completion of the twenty-five month AGD Master Track program at the University of Florida, with verified competency, to be completed within 30 months of the Final Order
- Three hours of Ethics completed through an accredited college to be completed within twelve (12) months of the Final Order
- Patient reimbursement of out-of-pocket fees and third party reimbursement if applicable, within twenty-four (24) months

Second: by Dr. Tejera Vote: Unanimous

iii. Harvey Adelson, DDS, Case No. 2015-09091(PCP – Thomas, Robinson, Fatmi)

Dr. Adelson was present and sworn in by the court reporter. He was represented by Randolph Collette, Esq.

Ms. Garrison summarized the case for the board. Respondent was charged with the following violations: Count I: Section 466.028(1)(x), Florida Statutes, by failing to take preoperative radiographs to perform the tooth extraction; by failing to correctly or accurately diagnose the patient's condition before rendering treatment; by failing to recognize the tooth's stability in the bone and cease or alter the mode of treatment during the procedure; and by having paid an indemnity in the amount of \$200,000.00 to the patient as a result of negligent conduct. **Count II:** Section 466.028(1)(m), Florida Statutes, by failing to maintain diagnostic findings justifying the course of treatment.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Letter of Concern
- \$7,500.00 fine to be paid within twelve (12) months

- Costs of \$3,631.04 to be paid within twelve (12) months
- Level I Exodontia course completed through an accredited college of dentistry within twelve (12) months.
- Level I Diagnosis and Treatment course completed through an accredited college of dentistry within twelve (12) months.
- Successful completion of the Laws and Rules exam within twelve (12) months

After discussion, the following action was taken:

Motion: by Dr. Tejera to accept Second: by Dr. Kochenour

Vote: Unanimous

iv. Veronica Thompson, DDS, Case No. 2014-16208(PCP – Fatmi, Thomas, Britten)

Dr. Thompson was present and sworn in by the court reporter. She was represented by George F. Indest, III, Esq. Dr. Thomas recused himself from this case and requested Dr. Tejera chair this tab.

Ms. Rochester summarized the case for the board. Respondent was charged with the following violations: **Count I:** Section 466.028(1)(x), Florida Statutes, by failing to obtain medical consultation from the patient's doctor prior to administering anesthesia; by failing to administer the proper amount of anesthesia; by failing to following the proper emergency protocols when patient went into cardiac arrest by not administering epinephrine; by failing to use an oropharyngeal airway or nasopharyngeal airway to improve ventilation; and by failing to administer flumazenil or naloxone to the patient. **Count II:** Rule 64B5-14.009(1) through a violation of Section 466.028(1)(gg), Florida Statutes, by failing to examine and record the patient's Mallampati Classification and Body Mass Index. **Count III:** Rule 64B5-14.009(1) through a violation of Section 466.028(1)(gg), Florida Statutes, by failing to record patient's vital signs every five minutes. **Count IV:** Rule 64B5-14.002(1) through a violation of Section 466.028(1)(gg), Florida Statutes, by failing to obtain a deep sedation permit prior to administering deep sedation.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Reprimand
- \$10,000.00 fine to be paid within six (6) months
- Costs of \$2,363.83 to be paid within six (6) months
- Voluntary relinquishment of Conscious Sedation permit and agrees to never apply for conscious sedation permit
- Patient reimbursement of out-of-pocket fees and third party reimbursement if applicable, within six (6) months
- Successful completion of the Laws and Rules exam within twelve (12) months

After discussion, the following action was taken:

Motion: by Dr. Kochenour to reject

Second: by Ms. Cabanzon

Vote: Unanimous

Motion: by Dr. Kochenour to impose revocation

Second: by Dr. Perdomo

Vote: 6/2

Mr. Indest requested the written offer of revocation.

The board took a recess at 12:20 p.m. to begin the Rule Hearing.

The board meeting reconvened at 2:40 p.m.

C. Voluntary Relinquishments

i. Victoria Kopfle, RDH, Case No. 2016-26288 (PCP – Thomas, Calderone, Cabanzon)

Ms. Kopfle was not present nor represented by counsel.

Ms. McDonnell summarized the case for the board. Respondent was charged with the following violations: **Count I:** Section 466.028(1)(mm), Florida Statutes, by intentionally violating Section 456.072(1)(v), Florida Statutes, by engaging or attempting to engage in sexual misconduct with patient. **Count II:** Section 466.028(1)(mm), Florida Statutes, by intentionally violating Section 456.072(1)(v), Florida Statutes, by engaging or attempting to engage in sexual misconduct with patient.

Motion: by Dr. Tejera to accept Second: by Dr. Kochenour

Vote: Unanimous

III. PETITION FOR RECONSIDERATION

A. Richard Lipman, DDS, Case No. 2015-09997

Dr. Lipman was present and sworn in by the court reporter. He was represented by Matthew Fischer, Esq.

Dr. Lipman's license was revoked at the February 17, 2017 meeting of the board. He filed a petition contesting the fact that he was served the Administrative Complaint and a Notice of Hearing at his address of record.

Motion: by Dr. Kochenour to keep the revocation in place.

Second: Dr. Miro Vote: Unanimous

IV. PROSECUTION REPORT

A. Bridget McDonnell, Assistant General Counsel

Ms. McDonnell provided her prosecution report to the board.

Motion: by Dr. Fatmi to allow prosecution to continue prosecuting year old cases.

Second: by Dr. Perdomo

Vote: Unanimous

Ms. McDonnell recognized Ms. Rochester as she will be moving on from the Department.

The Board thanked her for her dedication to the Board.

V. PETITION FOR DECLARATORY STATEMENT

A. Tatiana R. Oliveira, DDS

Dr. Oliveira was present and sworn in by the court reporter. She was represented by Cynthia Mikos, Esq.

Dr. Oliveira filed a Petition for Declaratory Statement for the board to consider whether she completed a supplemental general dentistry program as required by Section 466.006(3), Florida Statutes. Dr. Oliveira earned her DDS degree from Sao Paulo State University in Brazil, completed a one year mini-residency in Endodontics in 2009, and earned a Master of Science degree in Restorative Dentistry with a specialization in Endodontics in 2011. In 2014, she was accepted into Columbia University College of Dentistry's 24 month Postdoctoral Program in Endodontics and graduated in June 2016.

After discussion on the application, the following action was taken:

Motion: by Dr. Thomas to approve the licensure application.

The motion failed after there was no second. The board continued with more discussion regarding the requirements of the statute and decided to hear the petition first.

After further discussion, the following action was taken:

Motion: by Dr. Thomas to answer the petition in the negative due to her teaching experience not meeting the requirement of successfully completing a two year AEGD program as required by Section 466.006(3), Florida Statutes.

Second: Dr. Tejera Vote: Unanimous

Ms. Mikos requested to withdraw the application.

Motion: by Dr. Fatmi to accept Second: by Dr. Calderone

Vote: Unanimous.

VI. REVIEW OF APPLICATIONS

A. Applications for Dental License

i. Horace Ainsley Freeman, DDS

Dr. Freeman was present and sworn in by the court reporter. He was represented by Steven Brow, Esq. He has applied for a Florida dental license and answered "yes" to one of the discipline history questions as his previous Florida dental license was voluntary relinquished in February 2005.

After discussion, the following action was taken:

Motion: by Dr. Fatmi to grant the license

Second: by Dr. Tejera

Vote: 7/2

ii. Sameera Ahmed Qadri, DDS

Dr. Qadri was present and sworn in by the court reporter. She has applied for a Florida dental license and answered "yes" to one of the discipline history questions due to being involved in a civil litigation.

After discussion, the following action was taken:

Motion: by Dr. Tejera to approve

Second: by Dr. Calderone

Vote: Unanimous

iii. Jose Montero Nieto, DDS

This application was withdrawn from the agenda.

B. Application for Conscious Sedation Permit

i. Item Removed

VII. REQUEST FOR CONTINUING EDUCATION CREDIT

A. Paul Flaer, DDS

Dr. Flaer was not present nor represented by counsel.

He submitted a request to receive continuing education credit for articles he authored and published.

After discussion, the following action was taken:

Motion: by Dr. Thomas to grant twenty (20) hours of continuing education

Second: by Dr. Fatmi Vote: Unanimous

VIII. FOR YOUR INFORMATION

A. School-Based Sealant Programs

B. Talking Points on ADA's Development of an Objective Structured

Clinical Exam for Dental Licensure

- C. ADA's Proposed National OSCE Examination
- D. 2017 ADEX House of Representatives Meeting

IX. RULE DISCUSSION

A. Rule 64B5-13.0045 Minor Violations

- (1) Subject to the limitations imposed by this rule, the following violations are designated as minor for the purposes of Section 456.073(3), F.S.
- (a) Violation of Section 466.026(1)(a), F.S., by practicing for a period of less than two months without an active license.
- (b) Violation of Section 466.028(1)(d), F.S., by the following errors or omissions:
- 1. Violation of subsection 64B5-4.002(2), F.A.C.
- 2. Violation of subsection 64B5-4.003(2), (3), (4) or (5), F.A.C., so long as there is no allegation of consumer injury as a result of the violation and the advertisement which is in violation is capable of being withdrawn from circulation to the public within 15 days of issuance of the notice of noncompliance.
- (c) Violation of Section 466.028(1)(n), F.S., so long as the records have been released.
- (d) Violation of Section 466.028(1)(mm), F.S., by violating Rule 64B5-17.0011, F.A.C., which requires the licensee to notify the Board of changes of address.
- (e) Violation of Section 466.028(1)(dd), F.S., by presigning laboratory work order forms.
- (2) This designation of violations as minor for the purposes of Section 456.073(3), F.S., is limited to initial violations.
- (3) A monthly report of notices of noncompliance issued by the Department shall be reviewed by the Board to monitor the use and success of this procedure.

Motion: by Dr. Thomas to certify the minor violations listed in the rule

Second: by Ms. Cabanzon

Vote: Unanimous

The committee considered the economic impact and determined that a Statement of Estimated Regulatory Cost was not necessary and the rule will not need legislative ratification.

B. Rule 64B5-16.006 and 16.007 Remediable Tasks Delegable to a Dental Hygienist

64B5-16.006 Remediable Tasks Delegable to a Dental Hygienist

Through (2) No Change

(3)(c) Applying of topical fluorides that which are approved by the American Dental Association or the Food and Drug Administration, including the use of fluoride varnishes and silver diamine fluoride.

64B5-16.007 Levels of Supervision for Dental Hygienists

- (1) Through (3) no change
- (4) Without Supervision: Provide educational programs, faculty or staff training programs, authorized fluoride rise programs, apply fluoride varnishes <u>and silver diamine fluoride</u>, instruct patients in oral hygiene care and supervising patient oral hygiene care and other services which do not involve diagnosis or treatment of dental conditions.

The Board considered the economic impact and determined that a Statement of Estimated Regulatory Cost was not necessary and the rule will not need legislative ratification.

Motion: by Dr. Thomas Second: by Ms. Cabanzon

Vote: Unanimous

Dr. Miro was excused from the meeting.

C. CE for Teaching Permit Holders

The Board requested Rule 64B5-7.005 and 12.0135 be placed before the Rules Committee to be amended so the rules are consistent.

D. Rule 64B5-14 and Rule 64B5-15

64B5-14.001 Definitions.

- (1) Anesthesia The loss of feeling or sensation, especially loss of the sensation of pain.
- (2) (3) No Change
- (4) Moderate Conscious sedation A depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. This modality includes administration of medications via all parenteral routes, that is, intravenous, intramuscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal. The drugs, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
- (5) Pediatric Moderate Conscious Sedation A depressed level of consciousness produced by the administration of pharmacologic substances, that retains a child patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. This modality includes administration of medication via all parenteral routes; that is intravenous, intramuscular, subcutaneous, submucosal, or inhalation, and all enteral routes; that is oral, rectal, or transmucosal. The drugs, doses, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. For the purposes of this chapter, a child is defined as an individual under 18 years of age, or any person who has special needs, which means having a physical or mental impairment that substantially limits one or more major life activities.
- (6) (7) No Change
- (9) Office team approach A methodology employed by a dentist in the administration of general anesthesia, deep sedation, moderate conscious sedation, and pediatric sedation whereby the dentist uses one or more qualified assistants/dental hygienists who, working under the direct supervision of the dentist, assist the dentist, and assist

in emergency care of the patient.

- (10) Minimal Sedation (anxiolysis) The perioperative use of medication to relieve anxiety before or during a dental procedure which does not produce a depressed level of consciousness and maintains the patient's ability to maintain an airway independently and to respond appropriately to physical and verbal stimulation. This minimal sedation shall include the administration of a single enteral sedative or a single narcotic analgesic medication administered in doses appropriate for the unsupervised treatment of anxiety and pain. If clinically indicated, an opiod analgesic may also be administered during or following a procedure if needed for the treatment of pain. Except in extremely unusual circumstances, the cumulative dose shall not exceed the maximum recommended dose (as per the manufacturers recommendation). It is understood that even at appropriate doses a patient may occasionally drift into a state that is deeper than minimal sedation. As long as the intent was minimal sedation and all of the above guidelines were observed, this shall not automatically constitute a violation. A permit shall not be required for the perioperative use of medication for the purpose of providing minimal sedation (anxiolysis).
- (11) Titration of Oral Medication The administration of small incremental doses of an orally administered medication until an intended level of moderate conscious sedation is observed.
- (12) (14) No Change

64B5-14.002 Prohibitions.

- (1) General anesthesia or deep sedation. No dentists licensed in this State shall administer general anesthesia or deep sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this rule chapter.
- (2) <u>Moderate</u> Conscious sedation. No dentists licensed in this State shall administer moderate conscious sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this rule chapter.
- (3) Pediatric Moderate Conscious Sedation: No dentist licensed in this State shall administer Pediatric Moderate Conscious Sedation in the practice of dentistry until such dentist has obtained a permit as required by the provisions of this rule chapter.
 - (4) (6) No Change
- (7) Titration of Oral Medication. The Board of Dentistry has determined that the perioperative titration of oral medication(s) with the intent to achieve a level of moderate conscious sedation poses a potential overdosing threat due to the unpredictability of enteral absorption and may result in an alteration of the state of consciousness of a patient beyond the intent of the practitioner. Such potentially adverse consequences may require immediate intervention and appropriate training and equipment. Beginning with the effective date of this rule, no dentist licensed in this state shall use any oral medication(s) to induce moderate conscious sedation until such dentist has obtained a permit as required by the provisions of this rule chapter. The use of enteral sedatives or narcotic analgesic medications for the purpose of providing minimal sedation (anxiolysis) as defined by and in accordance with subsection 64B5-14.001(10), F.A.C., shall not be deemed titration of oral medication and shall not be prohibited by this rule.
- (8) The following general anesthetic drugs shall not be employed on or administered to a patient by a dentist unless the dentist possesses a valid general anesthesia permit issued by the Board pursuant to the requirements of this chapter: propofol, methohexital, thiopental, etomidate, ketamine, or volatile gases (i.e., sevoflurane, isoflurane).
- (9) A hygienist certified by the board to administer local anesthesia shall not administer local anesthesia to a patient sedated by general anesthesia, deep sedation, moderate eonscious sedation, or pediatric moderate eonscious sedation. If a dentist has administered nitrous-oxide to the patient, the certified dental hygienist may administer local anesthesia under the direct supervision of the supervising dentist. A patient who has been prescribed a medical drug by their licensed health care provider for the purposes of life functions may be administered local anesthesia by the certified dental hygienist under the direct supervision of the supervising dentist. If, however, the medical drug is prescribed or administered for the purposes of a dental procedure which is intended to induce minimal sedation (anxiolysis), the hygienist may not administer local anesthesia to the patient.

64B5-14.003 Training, Education, Certification, and Requirements for Issuance of Permits.

- (1) General Anesthesia Permit.
- (a) A permit shall be issued to an actively licensed dentist authorizing the use of general anesthesia or deep sedation at a specified practice location or locations on an outpatient basis for dental patients provided the dentist:
- 1. Has completed a minimum of a two year residency program accredited by the Commission on Dental Accreditation in dental anesthesiology or has completed an oral and maxillofacial surgical residency program accredited by the Commission on Dental Accreditation beyond the undergraduate dental school level; or
 - 2. Is a diplomate of the American Board of Oral and Maxillofacial Surgery; or
 - 3. Is eligible for examination by the American Board of Oral and Maxillofacial Surgery; or
 - 4. Is a member of the American Association of Oral and Maxillofacial Surgeons.
- (b) A dentist employing or using general anesthesia or deep sedation shall maintain a properly equipped facility for the administration of general anesthesia, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems and emergencies incident thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of general anesthesia or deep sedation requires at least three individuals, each appropriately trained: the operating dentist, a person responsible for monitoring the patient, and a person to assist the operating dentist.
- (c) A dentist employing or using general anesthesia or deep sedation and all assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing general anesthesia or deep sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).
- (d) A dentist permitted to administer general anesthesia or deep sedation under this rule may administer moderate eonscious sedation and nitrous-oxide inhalation moderate eonscious sedation.
- (e) A dentist employing or using deep sedation shall maintain an active and current permit to perform general anesthesia.
 - (2) Moderate Conscious Sedation Permit.
- (a) A permit shall be issued to a dentist authorizing the use of moderate eonscious sedation at a specified practice location or locations on an outpatient basis for dental patients provided such dentist:
 - 1. Has received formal training in the use of moderate conscious sedation; and
- 2. Is certified by the institution where the training was received to be competent in the administration of moderate conscious sedation; and
 - 3. Is competent to handle all emergencies relating to moderate conscious sedation.
- (b) Such certification shall specify the type, the number of hours, the number of patients treated and the length of training. The minimum number of didactic hours shall be sixty, which must include four (4) hours of airway management. Airway management must include emergency airway management protocols. Clinical training shall include personal administration for at least twenty patients including supervised training, clinical experience and demonstrated competence in airway management of the compromised airway. The program must certify that a total of three (3) hours of clinical training was dedicated to hands-on simulated competence in airway management of the compromised airway.
- (c) Personal Administration of Moderate Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergence, recovery, and approval for discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of moderate conscious sedation.
 - (d) This formal training program shall be offered through an accredited dental school or program; or through an

accredited, teaching hospital.

- (e) A dentist utilizing moderate conscious sedation shall maintain a properly equipped facility for the administration of moderate conscious sedation, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems, and emergencies incident thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of moderate conscious sedation requires at least two individuals: a dentist, and an auxiliary trained in basic cardiac life support. It shall be incumbent upon the operating dentist to insure ensure that the patient is appropriately monitored.
- (f) A dentist utilizing moderate conscious sedation and his assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing moderate conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).
- (g) Dentists permitted to administer moderate conscious sedation may administer nitrous-oxide inhalation moderate conscious sedation.
- (h) Dentists permitted to administer moderate conscious sedation may administer pediatric moderate sedation in compliance with Rule 64B5-14.010, F.A.C.
 - (3) Pediatric Moderate Conscious Sedation Permit.
- (a) A permit shall be issued to a dentist authorizing the use of pediatric moderate econscious sedation at a specified practice location or locations on an outpatient basis for dental patients provided such dentist:
- 1. Has received formal training in the use of pediatric moderate conscious sedation. This formal training program shall be offered through an accredited dental school or program; or through an accredited teaching program; and,
- 2. Is certified by the institution where the training was received to be competent in the administration of pediatric moderate conscious sedation. This certification shall specify the type, the number of hours, the number of patients treated and the length of training. The minimum number of didactic hours shall be sixty, which must include four (4) hours of airway management. Clinical training shall include personal administration for at least twenty patients including supervised training, management of sedation, clinical experience and demonstrated competence in airway management of the compromised airway. The program must certify that three (3) hours of clinical training was dedicated to hands-on simulated competence in airway management of the compromised airway; and
- 3. Personal Administration of Pediatric Moderate Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from preanesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergency, recovery, and approval for discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of pediatric moderate conscious sedation; or
- 4. The applicant demonstrates that the applicant graduated, within 24 months prior to application for the permit, from an accredited post-doctoral pediatric residency. The pediatric residency anesthesia requirements must meet the minimum number of sedation cases as required in subsection (2).
- 5. Is competent to handle all emergencies relating to pediatric moderate conscious sedation. A dentist utilizing pediatric moderate econscious sedation shall maintain a properly equipped facility for the administration of pediatric moderate conscious sedation, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems, and emergencies incidental thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of pediatric moderate conscious sedation requires at least two individuals: a dentist, and an auxiliary trained in basic cardiac life support. It shall be incumbent upon the operating dentist to insure ensure that the patient is appropriately monitored.
- (b) A dentist utilizing pediatric moderate conscious sedation and his assistant/dental hygienist personnel shall be Florida Board of Dentistry 17

certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric moderate conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), PALS (Pediatric Advanced Life Support), or a course providing similar instruction which has been approved by the Board. An entity seeking approval of such a course shall appear before the Board and demonstrate that the content of such course and the hours of instruction are substantially equivalent to those in an ACLS or PALS course.

- (c) Dentists permitted to administer pediatric <u>moderate</u> conscious sedation may administer nitrous-oxide inhalation moderate conscious sedation.
- (d) Dentists permitted to administer <u>moderate</u> <u>conscious</u> sedation may administer pediatric <u>moderate</u> <u>conscious</u> sedation.
 - (4) Nitrous-Oxide Inhalation Analgesia.
- (a) A dentist may employ or use nitrous-oxide inhalation analgesia on an outpatient basis for dental patients provided such dentist:
- 1. Has completed no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; or
 - 2. Has training equivalent to that described above while a student in an accredited school of dentistry; and
 - 3. Has adequate equipment with fail-safe features and a 25% minimum oxygen flow.
- (b) A dentist utilizing nitrous-oxide inhalation analgesia and such dentist's assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric moderate conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), ATLS (Advanced Trauma Life Support), or PALS (Pediatric Advanced Life Support).
- (c) A dentist who regularly and routinely utilized nitrous-oxide inhalation analgesia on an outpatient basis in a competent and efficient manner for the three-year period preceding January 1, 1986, but has not had the benefit of formal training outlined in subparagraphs 1. and 2. of paragraph (4)(a) above, may continue such use provided the dentist fulfills the provisions set forth in paragraph 3. of paragraph (4)(a) and the provisions of paragraph (b) above.
- (d) Nitrous oxide may be used in combination with a single dose enteral sedative or a single dose narcotic analgesic to achieve a minimally depressed level of consciousness so long as the manufacturer's maximum recommended dosage of the enteral agent is not exceeded. Nitrous oxide may not be used in combination with more than one (1) enteral agent, or by dosing a single enteral agent in excess of the manufacturer's maximum recommended dosage unless the administering dentist holds a moderate eonscious sedation permit issued in accordance with subsection 64B5-14.003(2), F.A.C., or a pediatric moderate eonscious sedation permit issued in accordance with Rule 64B5-14.010, F.A.C.
 - (5) No Change

64B5-14.0032 Itinerate/Mobile Anesthesia - Physician Anesthesiologist.

The provisions of this rule control the treatment of dental patients in an outpatient dental office setting where a physician anesthesiologist has performed the sedation services. This rule shall control notwithstanding any rule provision in this Chapter that prohibits such conduct. The level of sedation is not restricted to the level of the permit

held by the treating dentist. The level of sedation may be any level necessary for the safe and effective treatment of the patient.

- (1) No Change
- (2) Pediatric Moderate Conscious Sedation Permit Holders:

A pediatric dentist, as recognized by the American Dental Association, who holds a pediatric moderate eonseious sedation permit may treat their pediatric or special needs dental patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

- (a) The physician anesthesiologist performs the administration of the anesthesia, and the physician anesthesiologist is responsible for the anesthesia procedure;
 - (b) The treatment takes place in the permit holder's board-inspected and board-registered dental office;
- (c) The dental office meets the supply, equipment, and facility requirements as mandated in Rule 64B5-14.008, F.A.C.:
- (d) A board-approved inspector performs an inspection of the dental office and the inspector reports the office to be in full compliance with the minimum supply, equipment, and facility requirements.

A pediatric dentist who holds an active moderate eonscious sedation permit and not a pediatric moderate eonscious sedation permit shall meet the sedation permit requirement of this rule until the next biennial license renewal cycle that follows the effective date of this rule. At the next biennial license renewal cycle that follows the effective date of this rule, a pediatric dentist who hold a moderate conscious sedation permit may transfer the permit to a pediatric moderate conscious sedation permit without any additional cost besides the renewal fee.

(3) Moderate Conscious Sedation Permit Holders:

A dentist who holds a moderate conscious sedation permit may treat their adult or adult special needs dental patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

- (a) The physician anesthesiologist performs the administration of the anesthesia, and the physician anesthesiologist is responsible for the anesthesia procedure;
 - (b) The treatment takes place in the permit holder's properly board-inspected and board-registered dental office;
- (c) The dental office meets the supply, equipment, and facility requirements as mandated in Rule 64B5-14.008, F.A.C.;
- (d) A board-approved inspector performs an inspection of the dental office and the inspector reports the office to be in full compliance with the minimum supply, equipment, and facility requirements.
 - (4) (7) No Change

64B5-14.0034 Itinerate/Mobile Anesthesia – General Anesthesia Permit Holders.

The provisions of this rule control the treatment of dental patients in an outpatient dental office where a dentist with a general anesthesia permit performs the sedation services for a treating dentist. The treating dentist must possess a general anesthesia permit, moderate conscious sedation permit, or pediatric moderate conscious sedation permit. The level of anesthesia administered shall be to any level necessary to safely and effectively treat the dental patient. This rule shall control notwithstanding any rule provision in this Chapter that prohibits such conduct.

(1) General Anesthesia Permit Holder's Office:

A general anesthesia permit holder may perform sedation services for a dental patient of another general anesthesia permit holder or moderate conscious or pediatric moderate conscious sedation permit holder in his or her office or in another general anesthesia permit holder's office. In this setting, the following shall apply:

- (a) The dental treatment may only be performed by a treating dentist who holds a valid anesthesia permit of any level:
- (b). The treating dentist and the anesthesia provider are both responsible for the adverse incident reporting under Rule 64B5-14.006, F.A.C.
 - (2) Moderate Conscious and Pediatric moderate conscious Sedation Permit Holder's Office:

A general anesthesia permit holder may perform sedation services for a dental patient of another dentist who holds a <u>moderate</u> <u>conscious</u> sedation permit or a pediatric <u>moderate</u> <u>conscious</u> sedation permit at the office of the treating dentist. In this setting, the following shall apply:

- (a) The dental treatment may only be performed by the <u>moderate</u> eonscious sedation or pediatric <u>moderate</u> eonscious sedation permit holder;
- (b) The general anesthesia permit holder may perform general anesthesia services once an additional board-inspection establishes that the office complies with the facility, equipment and supply requirements of Rule 64B5-14.008, F.A.C.;
- (c) The treating dentist and the anesthesia provider are both responsible for the adverse incident reporting requirements under Rule 64B5-14.006, F.A.C.
 - (3) Equipment:

When the general anesthesia permit holder performs the anesthesia services in a dental office of a moderate conscious or pediatric moderate conscious sedation permit holder's office, the electrocardiograph and end tidal carbon dioxide monitor equipment mandates may be met as follows:

- (a) The general anesthesia permit holder provides the equipment which has already been inspected during the general anesthesia permit holder's required inspection;
 - (b) The equipment is available for inspection during the office's mandated inspection; and
 - (c) The equipment is immediately available for an adverse incident report inspection.
 - (4) (5) No Change

64B5-14.004 Additional Requirements.

- (1) Office Team A dentist licensed by the Board and practicing dentistry in Florida and who is permitted by these rules to induce and administer general anesthesia, deep sedation, moderate conscious sedation or nitrous-oxide inhalation analgesia may employ the office team approach.
- (2) Dental Assistants, Dental Hygienists Dental assistants and dental hygienists may monitor nitrous-oxide inhalation analgesia under the direct supervision of a dentist who is permitted by rule to use general anesthesia, moderate eonscious sedation, pediatric moderate rendering dental services allowed by Chapter 466, F.S., and under the following conditions:
- (a) Satisfactory completion of no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; and
- (b) Maintenance of competency in cardiopulmonary resuscitation evidenced by certification in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years.
 - (3) (4) No Change
- (5) A dentist utilizing moderate conscious sedation in the dental office may induce only one patient at a time. A second patient shall not be induced until the first patient is awake, alert, conscious, spontaneously breathing, has stable vital signs, is ambulatory with assistance, is under the care of a responsible adult, and that portion of the procedure requiring the participation of the dentist is complete. In an office setting where two or more permit holders are present simultaneously, each may sedate one patient provided that the office has the necessary staff and equipment, as set forth in paragraph 64B5-14.003(2)(d), F.A.C., for each sedated patient.
 - (6) No Change

64B5-14.005 Application for Permit.

(1) No dentist shall administer, supervise or permit another health care practitioner, as defined in Section 456.001, F.S., to perform the administration of general anesthesia, deep sedation, moderate conscious sedation or pediatric Florida Board of Dentistry

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moderate conscious sedation in a dental office for dental patients, unless such dentist possesses a permit issued by the Board. A permit is required even when another health care practitioner, as defined in Section 456.001, F.S., administers general anesthesia, deep sedation, moderate conscious sedation, or pediatric moderate conscious sedation in a dental office for a dental patient. The dentist holding such a permit shall be subject to review and such permit must be renewed biennially. Each dentist in a practice who performs the administration of general anesthesia, deep sedation, moderate conscious sedation or pediatric moderate conscious sedation shall each possess an individual permit. Nothing in this paragraph shall be construed to prohibit administration of anesthetics as part of a program authorized by Rule 64B5-14.003, F.A.C., any other educational program authorized by Board rule, for training in the anesthetic being administered, or pursuant to a demonstration for inspectors pursuant to Rule 64B5-14.007, F.A.C.

- (2) (4) No Change
- (5) An application for a moderate conscious sedation permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ moderate conscious sedation.
- (6) An application for a pediatric moderate conscious sedation permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ pediatric moderate conscious sedation.
- (7) The Board shall renew the permit biennially upon application by the permit holder, proof of continuing education required by subsection 64B5-14.004(6), F.A.C., and payment of the renewal fee specified by Rule 64B5-15.019, F.A.C., unless the holder is informed in writing that a re-evaluation of his credentials and facility is to be required. In determining whether such re-evaluation is necessary, the Board shall consider such factors as it deems pertinent including, but not limited to, patient complaints, reports of adverse occurrences and the results of inspections conducted pursuant to Rule 64B5-14.007, F.A.C. Such re-evaluation shall be carried out in the manner described in subsection (2) set forth above. A renewal fee of \$25.00 must accompany the biennial application.
- (8) The holder of any general anesthesia, <u>moderate</u> conscious sedation, or pediatric <u>moderate</u> conscious sedation permit is authorized to practice pursuant to such permit only at the location or locations previously reported to the Board office.

64B5-14.006 Reporting Adverse Occurrences.

- (1) Definitions:
- (a) Adverse occurrence means any mortality that occurs during or as the result of a dental procedure, or an incident that results in the temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment of a dental patient that occurred during or as a direct result of the use of general anesthesia, deep sedation, moderate conscious sedation, pediatric moderate conscious sedation, or local anesthesia.
- (b) *Supervising Dentist* means the dentist that was directly responsible for supervising the Certified Registered Dental Hygienist (CRDH) who is authorized by proper credentials to administer local anesthesia.
 - (2) (7) No Change

64B5-14.007 Inspection of Facilities and Demonstration of Sedation Technique.

(1) The Chairman of the Board or the Board by majority vote shall appoint consultants who are Florida licensed dentists to inspect facilities where general anesthesia, deep sedation, moderate conscious sedation, or pediatric moderate conscious sedation is performed. Consultants shall receive instruction in inspection procedures from the

Board prior to initiating an inspection.

- (2) Prior to issuance of a general anesthesia permit, moderate conscious sedation permit, or pediatric moderate conscious sedation permit, the applicant must demonstrate that he or she has knowledge of the use of the required equipment and drugs as follows:
- (a) Demonstration of General Anesthesia/Deep Sedation. A dental procedure utilizing general anesthesia/deep sedation must be observed and evaluated. Any general anesthesia/deep sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:
 - 1. Airway obstruction;
 - 2. Bronchospasm;
 - 3. Aspiration of foreign object;
 - 4. Angina pectoris;
 - 5. Myocardial infarction;
 - 6. Hypotension;
 - 7. Hypertension;
 - 8. Cardiac arrest;
 - 9. Allergic reaction;
 - 10. Convulsions;
 - 11. Hypoglycemia;
 - 12. Syncope; and
 - 13. Respiratory depression.
- (b) Demonstration of Moderate Conscious Sedation. A dental procedure utilizing moderate conscious sedation must be observed and evaluated. Any moderate conscious sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:
 - 1. Airway obstruction;
 - 2. Bronchospasm;
 - 3. Aspiration of foreign object;
 - 4. Angina pectoris;
 - 5. Myocardial infarction;
 - 6. Hypotension;
 - 7. Hypertension;
 - 8. Cardiac arrest;
 - 9. Allergic reaction;
 - 10. Convulsions;
 - 11. Hypoglycemia;
 - 12. Syncope; and
 - 13. Respiratory depression.
- (c) Demonstration of Pediatric Moderate Conscious Sedation. A dental procedure utilizing pediatric moderate conscious sedation must be observed and evaluated. Any pediatric moderate conscious sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:
 - 1. Airway obstruction;
 - 2. Bronchospasm;
 - 3. Aspiration of foreign object;
 - 4. Angina pectoris;
 - 5. Myocardial infarction;
 - 6. Hypotension;

- 7. Hypertension;
- 8. Cardiac arrest;
- 9. Allergic reaction;
- 10. Convulsions;
- 11. Hypoglycemia;
- 12. Syncope; and
- 13. Respiratory depression.
- (3) Any dentist who has applied for or received a general anesthesia permit, moderate conscious sedation permit, or pediatric moderate conscious sedation permit shall be subject to announced or unannounced on-site inspection and evaluation by an inspection consultant. This inspection and evaluation shall be required prior to issuance of an anesthesia permit. However, if the Department cannot complete the required inspection prior to licensure, such inspection shall be waived until such time that it can be completed following licensure.
- (4) The inspection consultant shall determine compliance with the requirements of Rules 64B5-14.008, 64B5-14.009 and 64B5-14.010, F.A.C., as applicable, by assigning a grade of pass or fail.
- (5) Any applicant who receives a failing grade as a result of the on-site inspection shall be denied a permit for general anesthesia anesthesia, and moderate conscious sedation and pediatric moderate sedation.
- (6) Any permit holder who fails the inspection shall be so notified by the anesthesia inspection consultant and shall be given a written statement at the time of inspection which specifies the deficiencies which resulted in a failing grade. The inspection team shall give the permit holder 20 days from the date of inspection to correct any documented deficiencies. Upon notification by the permit holder to the inspection consultant that the deficiencies have been corrected, the inspector shall reinspect to insure ensure that the deficiencies have been corrected. If the deficiencies have been corrected, a passing grade shall be assigned. No permit holder who has received a failing grade shall be permitted 20 days to correct deficiencies unless he voluntarily agrees in writing that no general anesthesia or deep sedation or moderate conscious sedation will be performed until such deficiencies have been corrected and such corrections are verified by the anesthesia inspection consultant and a passing grade has been assigned.
 - (7) (8) No Change
- (9) The holder of any general anesthesia, moderate conscious sedation, or pediatric moderate conscious sedation permit shall inform the Board office in writing of any change in authorized locations for the use of such permits prior to accomplishing such changes. Written notice shall be required prior to the addition of any location or the closure of any previously identified location.
- (10) Failure to provide access to an inspection team on two successive occasions shall be grounds for the issuance of an emergency suspension of the licensee's permit pursuant to the provisions of Section 120.60(8), F.S.

64B5-14.009 Moderate Conscious Sedation Requirements: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

<u>Moderate</u> <u>Conscious</u> Sedation Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

- (1) (6) No Change
- (7) Records: The following records are required when moderate conscious sedation is administered:
- (a) The patient's current written medical history, including known allergies and previous surgery;
- (b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
 - (c) Base line vital signs, including blood pressure, and pulse; and,
 - (d) A sedation or anesthesia record which shall include:
- 1. Continuous monitoring of vital signs, which are taken and recorded at a minimum of every 5 minute intervals during the procedure;

- 2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
 - 3. Duration of the procedure;
- 4. Documentation of complications or morbidity (See Rule 64B5-14.006, F.A.C., for Adverse Incident Reporting requirements);
 - 5. Status of patient upon discharge, and to whom the patient is discharged; and
 - 6. Names of participating personnel.
- (8) Continuous Monitoring: The patient who is administered a drug(s) for moderate conscious sedation must be continuously monitored intraoperatively by pulse oximetry, and capnograph to provide pulse rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide). A precordial/pretracheal stethoscope must be available to assist in the monitoring of the heart rate and ventilations.

64B5-14.010 Pediatric <u>Moderate</u> Conscious Sedation Requirements: Operatory; Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

Pediatric Moderate Conscious Sedation Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

- (1) (6) No Change
- (7) Records: The following records are required when pediatric moderate conscious sedation is administered:
- (a) The patient's current written medical history, including known allergies, history of previous surgery and anesthesia, and the patient's age, weight, and calculation of maximum allowable local anesthesia;
- (b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
- (c) Base line vital signs, including pulse, percent hemoglobin oxygen saturation, and when possible, blood pressure; and,
 - (d) An anesthesia or sedation record which shall include:
 - 1. Periodic vital signs recorded a minimum of every 5 minute intervals during the procedure;
- 2. Drugs, including local anesthetics, administered during the procedure, including route of administration, dosage, time and sequence of administration;
 - 3. Duration of the procedure;
- 4. Documentation of complications or morbidity (See Rule 64B5-14.0006, F.A.C., for Adverse Incident Reporting Requirements);
 - 5. Status of patient upon discharge, and to whom the patient is discharged; and,
 - 6. Names of participating personnel.
- (8) Continuous Monitoring: The patient who is administered a drug(s) for <u>pediatric moderate</u> eonscious sedation must be continuously monitored intra-operatively by pulse oximetry and capnograph to provide pulse rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide).

64B5-15.017 Application Fees for General Anesthesia, Pediatric Moderate Conscious Sedation, and Moderate Conscious Sedation Permits.

- (1) The application fee for a General Anesthesia Permit shall be \$100.00.
- (2) The application fee for a Moderate Conscious Sedation Permit shall be \$100.00.
- (3) The application fee for a Pediatric Moderate Conscious Sedation Permit shall be \$100.00.
- (4) Application fees are not refundable.

64B5-15.018 Initial Permit Fees for General Anesthesia, Pediatric Moderate Conscious Sedation, and Moderate Conscious Sedation Permits.

- (1) The initial fee for a General Anesthesia Permit shall be \$200.00.
- (2) The initial fee for a Moderate Conscious Sedation Permit shall be \$200.00.
- (3) The initial fee for a Pediatric Moderate Conscious Sedation Permit shall be \$200.00.
- (4) Initial permit fees may be refunded if the applicant is denied the permit without inspection.

64B5-15.019 Renewal Fees for General Anesthesia, Pediatric Moderate Conscious Sedation, and Moderate Conscious Sedation Permits.

- (1) The biennial renewal fee for a General Anesthesia Permit shall be \$200.00.
- (2) The biennial renewal fee for a Moderate Conscious Sedation Permit shall be \$200.00.
- (3) The biennial renewal fee for a Pediatric Moderate Conscious Sedation Permit shall be \$200.00.
- (4) Renewal fees are not refundable.

Motion: by Dr. Tejera to approve

Second: by Dr. Thomas

Vote: Unanimous

The Board considered the economic impact and determined that a Statement of Estimated Regulatory Cost was not necessary and the rule will not need legislative ratification.

- X. **NEW BUSINESS**
- XI. OLD BUSINESS
- XII. ADJOURNMENT

There being no further business, the meeting adjourned at 4:45 p.m.